

LEFFERT JAY & POLGLAZE

150 SOUTH FIFTH STREET,
SUITE 1900
MINNEAPOLIS, MINNESOTA 55402

Phone: 612.312.2200 Fax: 612.312.2250
www.fsplj.com

FAX COVER SHEET

To: U.S. PATENT AND TRADEMARK OFFICE
TC1600 - Before Final - 703 872 9306
From Daniel J. Polglaze, Reg. No. 39,801

FAX RECEIVED

SEP 17 2002

GROUP 1600

Fax: 703 872 9306 (Before Final)

Phone:

Date: September 16, 2002

Total Pages: 9

OFFICIAL

OUR REFERENCE: 101.003US01

RE: Serial No. 09/361,829
Applicant: Heath et al
Filing Date: July 27, 1999
Group Art: 1631
Examiner: Marianne P. Allen
Title: COMPUTER IMPLEMENTED NUCLEIC ACID ISOLATION METHOD
AND APPARATUS

Enclosed: Amendment and Response to Office Action (6 pages); and Transmittal (1 page).

**PLEASE DELIVER TO
EXAMINER Marianne P. Allen**

This Fax contains confidential information that may be attorney-client privileged. If you received this fax in error, please contact the sender at the above phone number and destroy the original.

S/N 09/361,829PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Heath, et al. Examiner: Marianne P. Allen
Serial No.: 09/361,829 Group Art Unit: 1631
Filed: July 27, 1999 Docket: 101.003US01
Filed CPA: March 11, 2002
Title: COMPUTER IMPLEMENTED NUCLEIC ACID ISOLATION METHOD
AND APPARATUS

#18
Plunkett
9/17/02

AMENDMENT AND RESPONSE

Commissioner for Patents
Washington, D.C. 20231

In response to the Office Action mailed May 16, 2002, Applicant responds as follows:

REMARKS

Applicant acknowledges with gratitude the acceptance of Continued Prosecution Application under 37 CFR 1.53(d) based on parent Application No. 09/361,829.

Claims 1-19 are pending in the application.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-5, 7, 9-13 and 15 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant strongly traverses this rejection, and submits that the original disclosure has full support for the claim amendments.

Claims 1, 7, 9, and 15 were amended to add reference to aspirating at a selectable aspiration rate or speed from gentle to vigorous. To support a rejection under § 112, the claim limitation alleged to not be described must be identified, and the Patent Office must "provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed."

Applicant: Heath, et al.
Filed: July 27, 1999
Title: COMPUTER IMPLEMENTED NUCLEIC ACID
ISOLATION METHOD AND APPARATUS

Serial No.: 09/361,829
Atty. Docket No.: 101.003US01

AMENDMENT AND RESPONSE

Page 2 of 6

Persons of ordinary skill in the field would have found that the Applicant was in possession of the invention at the time of the filing of the application on the basis of the disclosure therein, specifically as outlined above in the summary of the invention. MPEP 2163.04 places the burden on the Examiner to show and provide reasons why persons skilled in the art would not have recognized the description of the limitation in the disclosure of the application as filed. The Examiner has attempted to point out differences between the disclosure and the claim, but the differences are not actually present. In fact, Applicant submits that the disclosure as filed fully supports the amendment to claims 1, 7, 9, and 15 as discussed further herein.

Applicant submits that the function of aspiration mixing necessarily includes by inherency aspiration. Since aspiration mixing is accomplished at rates from gentle to vigorous, and since aspiration is described as having different rates available, different rate aspiration from gentle to vigorous is at least inherently disclosed in the application as originally filed. Page 6, lines 13-24 of the application read as follows:

Aspiration may be accomplished at different rates depending upon the desired result of the aspiration. It should also be understood that the process by which supernatant is removed may be varied, and that measurement of the volume may be by any known method, including but not limited to volume, weight, and the like, or that excess supernatant may be removed with remaining volume or mass as a determining factor. Such processes might include optically sensing the remaining material in the sample or the like.

Mixing is accomplished at various levels from gentle to vigorous. Mixing may be accomplished by any number of processes including physical agitation and a combination of aspirating and dispensing. Aspiration mixing is achieved by a cycle of aspirating and dispensing of fluid in and out of a pipette. Increasing and decreasing the aspiration and dispensation rates and volumes varies the mixing intensity.

From these lines, it is clear that the application in its original form contains sufficient subject matter to support the claims limitations added in the amendment of January 11, 2002, namely that aspiration is performed "at a selectable aspiration speed ranging from gentle to vigorous" or "at a selectable aspiration rate from gentle to vigorous." As the text of the application itself states, "[m]ixing is accomplished at various levels from gentle to vigorous. Mixing may be accomplished by any number of processes including ... a combination of

Applicant: Heath, et al.
Filed: July 27, 1999
Title: COMPUTER IMPLEMENTED NUCLEIC ACID
ISOLATION METHOD AND APPARATUS

Serial No.: 09/361,829
Atty. Docket No.: 101.003US01

AMENDMENT AND RESPONSE

Page 3 of 6

aspirating and dispensing. Aspiration mixing is achieved by a cycle of aspirating and dispensing fluid Increasing and decreasing the aspiration and dispensation rates and volumes varies the mixing intensity." (emphasis added).

As is clear from the actual text of the application, a selectable aspiration speed from gentle to vigorous is supported. The application states that mixing is accomplished by among other steps aspiration. Mixing is from gentle to vigorous. Since mixing can be from gentle to vigorous, and since aspiration is used in mixing, it is clear from the originally filed application that the support for the amendment is present in the originally filed application. Accordingly, Applicant submits that the rejection under 35 U.S.C. 112 is improper, as the application as originally filed includes full support for the amendment subject matter.

Aspiration is discussed as being available for different rates depending upon the desired result. This is sufficient support for aspiration at a range from gentle to vigorous. Increasing and decreasing aspiration rates is discussed in the specification. Any reading of the specification in context results in a clear finding that the material added by amendment of claims 1, 7, 9, and 15 is fully supported by the original specification. The specific phrase added by amendment to claims 7 and 15 is "at a selectable aspiration speed ranging from gentle to vigorous" and the specific phrase added by amendment to claims 1 and 9 is "at a selectable aspiration rate from gentle to vigorous." Each of these changes is directed to aspirating a sample. The specification clearly recites that aspiration may be accomplished at different speeds depending upon the desired result of the aspiration. This is clear support for aspiration at different speeds. Aspiration is used in mixing, in a combination of aspirating and dispensing during mixing. It is further explicitly stated that mixing is accomplished at various levels from gently to vigorous. It is further explicitly stated that increasing and decreasing the aspiration and dispensation rates and volumes varies the mixing intensity.

Since mixing is accomplishable at various rates from gentle to vigorous, and aspiration is accomplishable at different speeds for different results, and since aspiration is explicitly stated as part of the mixing process, it is at least inherent that aspiration can be accomplished at rates from gentle to vigorous. To find any differently is to ignore the direct teachings of the original specification.

Applicant: Heath, et al.
Filed: July 27, 1999
Title: COMPUTER IMPLEMENTED NUCLEIC ACID
ISOLATION METHOD AND APPARATUS

Serial No.: 09/361,829
Atty. Docket No.: 101.003US01

AMENDMENT AND RESPONSE

Page 4 of 6

While the specification may not explicitly state that aspiration is accomplishable at a speed ranging from gentle to vigorous, it is all but explicit. Only a reading of one sentence of the specification without resort to the rest of the teachings of the specification would result in a statement that the amendment subject matter was not present in the original specification.

Each of claims 2-5 and 10-13 depend from and further define patentably distinct claim 1 or 9, and as such are believed allowable for the reasons set forth in support of the allowance of their base claims.

The subject matter of the amendments to claims 1, 7, 9, and 15 was present in the specification of the application as originally filed. As such, the Office Action fails to state a proper new matter rejection, and Applicant respectfully submits that the rejections of the claims cannot stand.

Claim Rejections Under 35 U.S.C. § 102

Claims 6, 8, 14 and 16-18 were rejected under 35 U.S.C. §102(b) as being anticipated by Petschek et al. (U.S. Patent No. 5,389,339). Applicant traverses this rejection, and submits that Petschek et al. does not contain each and every element of the claims.

Petschek et al. is described extensively in its disclosure as an integral device, and the disclosure touts the integral device and all the alleged attendant advantages of an integral machine. This is not what is claimed by Applicant. In fact, claims 1-9, 10, 14, and 16-18 are directed to "a computer readable medium," "a control module," "a computer system," or "a computer control module," each of the claims being specifically for the control or operation of a device for automated nucleic acid isolation. Petschek et al. discloses an integral machine, not a control module, a computer system, a computer readable medium, or a computer control module for operating a machine. Petschek et al. is the machine itself. To remove a singular component of a device (Petschek et al.'s device) that is disclosed and taught as an integral device goes against the very teachings of Petschek et al.

Petschek et al. teaches nothing more than a centrifuge with dispensing capability, a general centrifuge-based device for automating separation. The present claims describe the computer system and system protocols needed to cause a device to perform much more

Applicant: Hearth, et al.
Filed: July 27, 1999
Title: COMPUTER IMPLEMENTED NUCLEIC ACID
ISOLATION METHOD AND APPARATUS

Serial No.: 09/361,829
Atty. Docket No.: 101.003US01

AMENDMENT AND RESPONSE

Page 5 of 6

complex functions than the device of Petschek et al. could perform. The device of Petschek et al. would not be able to perform the functions that the computer system and protocols of the claims recite because the functions of Petschek et al. are performed within the centrifuge rotor, and the disclosure describes no means by which the device could be interfaced and programmed. Petschek is meant "to automate the basic preparation procedures known in the art at the time."

Claim Rejections Under 35 U.S.C. § 103

Claims 1-9, 10, 14-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464). As Applicant has mentioned, Petschek et al. is an integral device that cannot be divorced from its integral nature without destroying the functionality of the device. A modification that would change the main device into something that is substantially different and has a different operation is not a proper use of a combination under section 103. As such, the integral machine nature of Petschek et al. does not allow a part of the integral device to be removed from the device and combined with another device to create a proper rejection under section 103. It is therefore improper to combine Petschek et al. and Lange.

Claims 9, 11, 14 and 19 were further rejected under 35 U.S.C. §103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Johnson et al. (U.S. Patent No. 5,584,039). The improper combination of Petschek et al. and Lange has been discussed above. Nothing in Johnson et al. adds anything further to the analysis of Petschek et al in combination with Lange, and as such, this combination is also improper.

Claims 9 and 12 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Petschek et al (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Poulter et al (U.S. Patent No. 6,072,795). The improper combination of Petschek et al. and Lange has been discussed above. Nothing in Poulter et al. adds anything

Applicant: Heath, et al.
Filed: July 27, 1999
Title: COMPUTER IMPLEMENTED NUCLEIC ACID
ISOLATION METHOD AND APPARATUS
AMENDMENT AND RESPONSE

Serial No.: 09/361,829
Aux. Docker No.: 101.003US01

Page 6 of 6

further to the analysis of Petschek et al in combination with Lange, and as such, this combination is also improper.

Claims 9 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of McNutt (U.S. Patent No. 5,802,389). The improper combination of Petschek et al. and Lange has been discussed above. Nothing in McNutt adds anything further to the analysis of Petschek et al in combination with Lange, and as such, this combination is also improper.

CONCLUSION

Claims 1-19 remain pending in the application. Applicant believes that all of the claims are in condition for allowance and respectfully requests a Notice of Allowance be issued in this case. If the Examiner has any questions regarding this application, please contact the undersigned attorney at (612) 312-2203.

Respectfully submitted,

Date: 16 Sept 2002



Daniel J. Polglaze

Reg. No. 39,801

Attorneys for Applicant
Leffert Jay & Polglaze
P.O. Box 581009
Minneapolis, MN 55458-1009

Telephone: 612-312-2200
Fax: 612-312-2250
Direct Phone: 612-312-2203